

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL : MDL No. 2804
PRESCRIPTION OPIATE :
LITIGATION : Case No. 17-md-2804
:
APPLIES TO ALL CASES : Hon. Dan A. Polster
:
:

HIGHLY CONFIDENTIAL

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - - -

JANUARY 8, 2019

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VIDEOTAPED DEPOSITION OF GREGORY CARLSON,
taken pursuant to notice, was held at Marcus &
Shapira, One Oxford Center, 35th Floor, Pittsburgh,
Pennsylvania 15219, by and before Ann Medis,
Registered Professional Reporter and Notary Public in
and for the Commonwealth of Pennsylvania, on Tuesday,
January 8, 2019, commencing at 9:06 a.m.

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1 was complying with the Controlled Substances Act
2 between 2009 and 2014 whether HBC had any policies
3 in writing during that timeframe?

4 MR. BARNES: Object to form.

5 THE WITNESS: They had procedures in
6 writing.

7 BY MR. ROTTINGHAUS:

8 Q. Now you're using procedures, not
9 policies. So I want to make sure I'm not getting
10 confused.

11 A. It's a definition from a Giant Eagle
12 definition standpoint. So you can define policies
13 and procedures however you want. We had
14 procedures documented.

15 When we went to get our DEA license, we had
16 to have procedures documented. Otherwise, they
17 would not have approved. The DEA approved our
18 facility to be licensed. We had to have the
19 required documentation and procedures put together
20 on paper, and we showed them to the DEA officers
21 who came in and inspected the facility prior to
22 using it. And all of our procedures matched up
23 with the Controlled Substances Act.

24 Q. And these are in writing?

25 A. They were in writing.

1 weekly movement, monthly movement, things like
2 that.

3 Q. Were you personally tasked with the
4 responsibility to review the daily movement
5 reports to identify any movements of suspicious
6 quantities of substances, or was there some other
7 place to assist you in that?

8 MR. BARNES: Object to form.

9 THE WITNESS: There were other systems.
10 I can't remember which reports that would flag
11 certain things. The one I was speaking of was
12 just a general second level safeguard where I can
13 see if any movements were out of line from
14 previous history.

15 But there were other reports -- I can't think
16 of the names of those reports -- that were out
17 there that would look at movements of therapeutic
18 categories of drugs specifically.

19 BY MR. ROTTINGHAUS:

20 Q. So you at this point in time, from 2009
21 to 2014, sometime during that timeframe, you
22 became a senior director of pharmacy?

23 A. Yes.

24 Q. And when you became the senior director
25 of pharmacy, were you overseeing all 200 something

1 Giant Eagle stores?

2 A. No, not the stores. I was overseeing
3 all of corporate functions at that point. So
4 Anthony Mollica was still in charge of the
5 operations of the stores. I was responsible for
6 the contract management of any vendors, the
7 managed care side, which is the insurance
8 contracting piece of it kind of rolled up
9 underneath me as well. So it was more at that
10 level.

11 Q. And I just want to make sure I
12 understand. During this timeframe from 2009 to
13 2014, you're telling us that one of the processes
14 in place was you would get a sheet of daily
15 movement of all of your medications, including
16 controlled substances, and you would personally
17 look through that to try to identify any orders
18 that seemed out of the ordinary?

19 A. We had buyers.

20 Q. First of all, am I correct in what I
21 said? If I'm not, just correct me.

22 A. Oh, no, I mean, I didn't daily look at
23 those reports. We had buyers in place at that
24 time. We had a category manager in place at the
25 time. So they would use that to generate their --

1 as part of their reordering process. So when we
2 reviewed that, they could also see any out of the
3 norm patterns in that process.

4 Q. And you're saying you're one of the
5 individuals that was reviewing and tasked and
6 responsible for reviewing for any out of the norm
7 patterns?

8 A. I didn't. When you mentioned senior
9 director of pharmacy, no, I was not reviewing the
10 reports at that time.

11 Q. And that would have been between 2005 --

12 A. Right.

13 Q. I'm sorry. 2007 and 2012.

14 A. No senior director of pharmacy.

15 Q. 2012 to 2014.

16 A. Correct.

17 Q. You were not doing so?

18 A. I was not reviewing the daily reports
19 back at that point.

20 Q. Who was reviewing the daily reports at
21 that time, if anyone?

22 A. Kris Remas would have been reviewing
23 reports as part of -- again, our daily process was
24 to review the reports.

25 Q. Now, when those reports would get

1 certain, but I do remember threshold emails coming
2 from McKesson.

3 BY MR. ROTTINGHAUS:

4 Q. And actually threshold criteria started
5 to get set for HBC as of 2013; is that right?

6 A. There was a report created, an automated
7 report created at that time.

8 Q. Whose idea was it to create that report?

9 A. I'm not sure who came up with the idea,
10 but it was a team that kind of worked on how do we
11 come up with a process to do that.

12 Q. Why was the team trying to come up with
13 a process to identify thresholds at HBC warehouse?

14 A. We were trying to enhance and improve
15 our process along the way.

16 Q. The process of identifying orders that
17 might be in excess of ordinary?

18 A. It would be targeting not orders
19 specifically. Thresholds don't catch one order.
20 Thresholds capture patterns of orders. So one
21 large is not, unless it exceeds the threshold, is
22 not going to be caught by the threshold.

23 Q. What if it exceeded the threshold, what
24 did you expect to happen?

25 A. The order would be investigated.

1 Q. How would it be investigated?

2 A. There would be a number of people that
3 would find out what was going on with that store
4 in particular that would do -- down at the PDL
5 level, district leader level investigating what
6 was going on at that particular store.

7 Q. So this level started below you where
8 the investigation would start?

9 A. Below me and the operations department
10 would go and look at what's going on in the store.

11 Q. That's what I want to understand, is
12 what your system was, who the people were that
13 were eyeing these threshold reports and then
14 reporting to whoever they reported to if there
15 were orders exceeding thresholds and then what due
16 diligence was done.

17 A. So the overall security efforts of the,
18 you know -- to meet the needs of this particular
19 act or regulation encompassed many different parts
20 of the whole process. So it would be -- we looked
21 at ourselves as a self distributor. We had owned
22 the product, and we're basically handing it off to
23 another location within our chain.

24 Unlike a wholesaler, which is selling to a
25 new customer, a different customer, self

1 distribution, we knew our customers because they
2 were us. So we were very familiar with our
3 customers. We knew exactly what was going on.
4 Each of these prescriptions were dispensed with a
5 valid prescription. So those were kind of the
6 added security measures that met the needs of the
7 requirement.

8 Q. Are you able to sit here under oath
9 today and tell us that every one of the
10 prescriptions that HBC warehouse filled were
11 filled with a valid prescription?

12 MR. BARNES: Object to form.

13 THE WITNESS: The HBC warehouse filled?

14 BY MR. ROTTINGHAUS:

15 Q. Yes.

16 A. You mean the product coming from HBC
17 warehouse?

18 Q. Yes.

19 A. I can't state, you know, something like
20 that.

21 Q. I thought I heard you say that. I
22 understand that you can't say that. I'm just
23 wondering -- if you're able to say it, I wonder
24 how.

25 A. We act under the guise that our process

1 BY MR. ROTTINGHAUS:

2 Q. Would one benefit of the documentation
3 be the ability to show any regulatory body that
4 HBC did indeed take steps to maintain a system, to
5 implement, design and operate a system to disclose
6 the presence of suspicious orders?

7 A. When we opened HBC, we received our DEA,
8 we were inspected by the DEA. They came in. They
9 looked at all of our security features related to
10 this Controlled Substances Act, looked at all of
11 our processes.

12 Our security, according to them, fit all
13 requirements, all the needed necessary steps. We
14 were acting upon that. There was nothing in the
15 provision that said we had to keep documentation
16 for any period of time on any investigation.

17 We did our process. If there was any
18 suspicion come up, we investigated it thoroughly,
19 made our decision. And I can't even think of a
20 time where we -- maybe there was a couple, but not
21 that I can recall, an example when there was a
22 suspicious order that we actually defined. I'm
23 not saying it didn't happen, but I can't recall an
24 example.

25 MR. ROTTINGHAUS: Object and move to

1 did you understand that to include an overall
2 evaluation of the adequacy of the controls at the
3 HBC and store levels?

4 A. Yes.

5 Q. Do you understand that the regulation
6 that you were shown by plaintiffs' counsel is just
7 one small aspect of the overall security
8 requirement?

9 A. Correct, yes.

10 Q. And do you understand that 1301.74
11 requires that HBC operated a system to disclose
12 suspicious orders?

13 A. Yes.

14 Q. Did you ever understand it to require
15 any type of formulaic or threshold system?

16 A. No.

17 Q. At the warehouse level, I just want to
18 explore what you do understand. You mentioned
19 cages, things of that nature.

20 Were these control IIIs, IVs, and Vs kept in
21 locked cages?

22 A. Yes, per the DEA requirements of
23 specifically around the cage.

24 Q. You said the DEA actually reviewed the
25 HBC security system before it opened and started

1 distributing control IIIs, IVs, and Vs?

2 A. Yes, before they approved our DEA
3 license.

4 Q. And did they come in from time to time
5 to reaudit and inspect?

6 A. Yes.

7 MR. ROTTINGHAUS: Objection. Leading.

8 BY MR. BARNES:

9 Q. At any time, did the DEA ever advise HBC
10 that there was anything lacking in their control
11 system?

12 MR. ROTTINGHAUS: Objection.

13 Foundation.

14 THE WITNESS: There was nothing pointed
15 out within our security measures that didn't meet
16 the requirements.

17 BY MR. BARNES:

18 Q. Did Giant Eagle ever distribute to
19 internet pharmacies?

20 A. No.

21 Q. By Giant Eagle I'm including HBC.

22 A. No, we did not.

23 Q. But you've also told us that you don't
24 really know the details -- you said the pickers
25 were regulated in terms of access to the cages; is

1 that right?

2 A. Yes.

3 Q. But the detailed procedures of how they
4 actually did their picking and the forms they
5 filled out, that wasn't part of your job?

6 A. No, it was not.

7 Q. Were inventories conducted at HBC?

8 A. Yes.

9 Q. Regular inventories?

10 A. Yes.

11 Q. Was the HBC warehouse overseen by Giant
12 Eagle's internal audit and accounting department?

13 MR. ROTTINGHAUS: Objection. Leading.

14 THE WITNESS: Yes.

15 BY MR. BARNES:

16 Q. You were asked a lot of questions today
17 about the development of a so-called SOM system in
18 2013 or 2014. Do you recall that?

19 A. Yes.

20 Q. Was that threshold system I'll call it,
21 was that developed because there was any view that
22 the currently existing controls that you describe
23 were viewed as inadequate in any way?

24 A. No. They were put together as an
25 enhancement to the current process.

1 Q. And that process, that threshold process
2 began in or about 2013?

3 A. About per my recollection.

4 Q. And were enhancements made to that
5 process over time?

6 A. Yes.

7 Q. Are you familiar with the CSOS system?

8 A. Yes.

9 Q. Is that one of the enhancements?

10 A. CSOS was a system that just assisted in
11 ordering CII through at the time it was the
12 wholesaler process, but it was -- it helped us --
13 it was an enhancement for ordering CIIs, so from
14 that perspective.

15 Q. Are you familiar with Supply Logics?

16 A. Yes.

17 Q. Was that an enhancement to the threshold
18 system?

19 A. Yes.

20 Q. What did Supply Logics allow you to do?

21 A. Supply Logics had a couple components to
22 it that could allow us to audit and monitor. So
23 it would -- I can't remember. I'm trying to
24 visualize what this report looked like, but it
25 would -- it basically would pull out -- allow us

1 to evaluate, investigate stores that were -- you
2 know, that stuck out in some fashion.

3 Q. At the pharmacy level you talked a
4 little bit about some of the controls at that
5 level.

6 I just want to ask you generally. Were all
7 of the pharmacies staffed by licensed and trained
8 pharmacists?

9 A. Yes.

10 Q. Were they staffed by trained
11 technicians?

12 A. Yes.

13 Q. Were all of those individuals trained
14 with respect to diversion?

15 A. There was a component of the training --
16 I don't know specifically, but I know there were
17 some discussions in the training around that.

18 Q. Were there policies and procedures,
19 written policies and procedures in place at the
20 pharmacy level that assisted the pharmacists and
21 technicians with respect to filling appropriate
22 prescriptions?

23 A. Yes.

24 Q. Are you familiar with the DEA pharmacist
25 manual?

1 MR. ROTTINGHAUS: Objection. Relevance.

2 THE WITNESS: I may have seen it. I
3 can't recall.

4 BY MR. BARNES:

5 Q. Do you recall if that was located at the
6 pharmacies or accessible by the pharmacies?

7 A. Yeah. That should have been at each
8 location, I believe.

9 Q. Did Giant Eagle have controlled
10 substance dispensing guidelines?

11 A. There were guidelines around controlled
12 substances, yes.

13 Q. Did it include things like red flags,
14 things to look out for before dispensing and
15 filling a prescription?

16 A. Yes.

17 MR. ROTTINGHAUS: Are you talking about
18 at the pharmacy level or HBC level?

19 MR. BARNES: Pharmacy level.

20 BY MR. BARNES:

21 Q. Are you familiar with the so-called
22 OARRS system?

23 A. Yes.

24 Q. What is that?

25 A. It's an Ohio system to monitor

1 prescription dispensing across the whole state.

2 Q. Is that something to your knowledge the
3 Giant Eagle pharmacists would access when filling
4 a prescription as necessary?

5 A. Yes, as required.

6 MR. ROTTINGHAUS: I didn't want to
7 interrupt. I'm interposing an objection on
8 relevance grounds.

9 BY MR. BARNES:

10 Q. Did the pharmacists or do the pharmacies
11 report their transactions to the DEA? I think you
12 already testified to that concerning the ARCOS
13 system.

14 A. The ARCOS was one way. We also reported
15 dispensings through like the OARRS system and all
16 that. That was done at corporate level, but all
17 that information about the stores came from
18 corporate that was provided.

19 Q. Did Giant Eagle have written fraud,
20 waste and abuse guidelines and procedures that
21 were at the pharmacies?

22 A. Yes.

23 Q. The record keeping at the pharmacies,
24 are you familiar with the term controlled
25 substance boxes that maintain records?

1 A. Yes.

2 Q. Is that something when you were a PDL
3 you had to make sure every pharmacy complied with?

4 A. The boxes either came out like right
5 when I was going onto my other position, the
6 physical boxes that you're talking about. It
7 was -- I didn't physically do that as a PDL. I
8 think it came out just as I went on to my next
9 position.

10 Q. But in your next position, did you learn
11 what those were?

12 A. Yes.

13 Q. What were they for generally?

14 A. Just to kind of keep everything in one
15 place around controlled substances.

16 Q. Would those include DEA forms, records
17 of invoices and transactions on controlled
18 substances?

19 A. DEA 222 forms, invoices, anything
20 regarding controlled substances.

21 Q. At the pharmacy level, were the
22 controlled substances handled any differently than
23 any other drug?

24 A. Were they handled differently? Yes.

25 Q. Were they kept in a secure location?

1 A. Any of the Schedule II were kept in a
2 locked location that only the pharmacist had
3 access to.

4 Q. And who could fill a controlled
5 substance II level prescription at the pharmacies?
6 Could a tech do it, or was it a pharmacist
7 required?

8 MR. ROTTINGHAUS: Objection. Relevance.

9 THE WITNESS: A pharmacist was required
10 to do that process.

11 BY MR. BARNES:

12 Q. And how were incoming orders of
13 controlled substances handled? Were there special
14 procedures for those?

15 A. Yeah. We had formalized processes or
16 procedures drawn up on how to receive an order,
17 and it even broke out controlled substances and
18 how to handle those orders specifically.

19 Q. Were those orders checked against
20 invoices and immediately logged into inventory?

21 A. Yes.

22 Q. Were there regular and then perpetual
23 inventories of all controlled substances?

24 A. Yes. There were Schedule IIIs through
25 Vs were part of our perpetual. The CIIs were done

1 in a manual fashion. So we're talking 2009 to
2 '14. It became part of the perpetual throughout
3 that time period.

4 Q. You mentioned monthly narc audits. Was
5 that for all controlled substances?

6 A. Yes.

7 Q. And were there also annual controlled
8 substance inventories on top of the monthly narc
9 audits?

10 MR. ROTTINGHAUS: Objection. Leading.

11 THE WITNESS: I'm sorry. Say that
12 again.

13 BY MR. BARNES:

14 Q. In addition to the monthly narc audits,
15 were there regular annual inventories?

16 MR. ROTTINGHAUS: Same objection.

17 THE WITNESS: Yeah. We were required to
18 do an every two-year inventory. We actually did
19 ours on an annual basis.

20 BY MR. BARNES:

21 Q. While controlled substance prescriptions
22 were being filled, were there special accounting
23 procedures employed to maintain control over every
24 pill?

25 A. Yes.

1 MR. ROTTINGHAUS: Objection. Leading.

2 BY MR. BARNES:

3 Q. Did the Ohio -- not only Ohio, but did
4 the state Boards of Pharmacy come into the
5 pharmacies on a random and unannounced basis and
6 perform surprise inspections on a routine basis?

7 A. Yes.

8 Q. Were there ever any problems that you
9 can recall involving controlled substances or
10 opioids?

11 A. Nothing specific to an inspection
12 regarding those products.

13 Q. And you were a PDL for a while?

14 A. Yes.

15 Q. And you had a region where you regularly
16 visited all your stores?

17 A. Yes.

18 Q. Were all of the pharmacies supervised by
19 a PDL in some way?

20 A. Yes.

21 Q. And did they regularly visit the store
22 and conduct audits from time to time?

23 A. Yes.

24 Q. And did that include controlled
25 substance procedures?

1 A. Yes.

2 Q. Did the PDL supervise training at the
3 pharmacies?

4 A. Not directly supervise, but ensure that
5 all team members within that unit were trained.

6 Q. Did the PDLs work with law enforcement
7 and the Board of Pharmacy to deter diversion and
8 prosecute criminals?

9 MR. ROTTINGHAUS: Objection. Leading.

10 THE WITNESS: Yes.

11 BY MR. BARNES:

12 Q. Did the PDLs exercise red flag awareness
13 training in the pharmacies?

14 A. Yes.

15 Q. Would the PDLs have an opportunity to
16 observe while in these pharmacies suspicious
17 activity, such as long lines out the door, things
18 of that nature?

19 A. Yes.

20 Q. And I think you said when you were a
21 PDL, you would assist from time to time with
22 threshold increases if the stores needed them;
23 right?

24 A. When I was a PDL -- that was after I was
25 a PDL when I was actually having the PDLs do the

RE-EXAMINATION

BY MR. BARNES:

Q. Just one follow-up question. After the threshold daily report was instituted in or about October of '13, did it reveal anything with respect to the adequacy of the controls that were already in place?

A. Based on --

MR. ROTTINGHAUS: Let me make a quick objection. Insufficient foundation.

But go ahead.

THE WITNESS: Based on the limited number of suspicious orders that were generated afterwards, I would say, no, it didn't really add a whole lot to the process. But, again, we looked at it as an enhancement to what we had in place, an extra stopgap.

BY MR. BARNES:

Q. Did it indicate one way or the other whether the controls in place were adequate?

A. I would evaluate it --

MR. ROTTINGHAUS: Objection. Leading.

THE WITNESS: I would evaluate it to show that we did have adequate controls in place from the beginning.

1 BY MR. BARNES:

2 Q. Even after you instituted -- you
3 enhanced it with the threshold system?

4 A. Yes.

5 MR. BARNES: Nothing further.

6 RE-EXAMINATION (Continued)

7 BY MR. ROTTINGHAUS:

8 Q. Prior to 2014, was there ever a system
9 in place where anyone at HBC was instructed when
10 they had an order that exceeded thresholds to ask
11 any particular questions of the pharmacy to find
12 out and do a little more due diligence as to why
13 the order was exceeding threshold?

14 A. When you say threshold, HBC wasn't
15 looking at threshold information. They would look
16 at unusual orders, being a large size, and that's
17 where they would ask the questions from.

18 Q. And was there ever at any point in time
19 to your knowledge any documented instruction to
20 anyone at or on behalf of HBC as to what specific
21 questions they should be asking of pharmacies when
22 they have an order that they thought was
23 extraordinarily large?

24 A. Their process was to notify myself or
25 someone else at corporate to do the investigation